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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/056,136	01/24/2002	Nobuyuki Tatsumi	NGB-12930	2328

40854 7590 07/28/2006

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EXAMINER	
GORDON, BRIAN R	

ART UNIT	PAPER NUMBER
1743	

DATE MAILED: 07/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/056,136	TATSUMI, NOBUYUKI	
	Examiner	Art Unit	
	Brian R. Gordon	1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *7-18-06*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3,16 and 18* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *1, 18* is/are allowed.

6)☒ Claim(s) *3 and 16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *1-24-02* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

Applicant's arguments, see remarks, filed July 18, 2006, with respect to the rejection(s) of claim(s) 3 and 16 have been fully considered and are not persuasive.

Applicant has amended the claims to include a negative limitation as to assert only the outer surface of the needle is coated. Applicant further asserts, "Palasis et al. teaches that metallic components are frequently used to carry pharmaceutically active materials, but that contact between the pharmaceutically active material and the metallic component should be avoided because of incompatibility (see col. 1, lines 13-34). To avoid the incompatibility issues, Palasis et al. teaches that the metallic component should be modified by providing it with a surface treatment that prevents contact between the pharmaceutically active material and the metallic component, or that the metallic component should be replaced entirely with a more inert metallic component or a polymeric component such as PEEK (see col. 2, lines 30-52)."

The examiner respectfully disagrees with applicant. Palasis et al. as pointed out by applicant does disclose "Medical devices having metallic components are used extensively in the medical field. In many cases the medical device is used for delivery of a pharmaceutically active material, and the pharmaceutically active material comes into contact with the metallic component during the course of delivery of the pharmaceutically active material. For example, metallic lumens are frequently used to carry pharmaceutically active materials to various bodily tissues. As another example, metallic stents having a drug delivery polymer coating thereon are used for delivery of

pharmaceutically active materials." (Background of Invention). This passage alone establishes that it is well know for the metal coated devices to be employed. There is no mention that these devices should be "avoided" as stated by applicant. The disclosure simply states that upon the choice to use such devices it may be beneficial to coat the entire surface. There is no such teaching within the reference that one should absolutely or completely avoid the uncoated metallic surfaces of the devices which are already known to have existed and used to transfer materials.

The teachings of Palasis et al. are similar to that of applicant. For on Page 9, line 20, applicant teaches the use of a not coated surface may be a reason of concern for cross contamination to occur. So is this an indication that such a surface should not be used? On page 10, applicant admits it's an improvement to coat the inner surface rather than leave it not coated. But as evidenced by applicant's claim to such an uncoated device it remains possible to use such an uncoated device eventhough the risk of cross contamination exists. Based on applicant's interpretation and applying such guideline's to applicant's teachings it would appear that applicant's specification also teaches away from using an uncoated surface.

For reasons given herein, the examiner hereby maintains the previous rejections.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 3 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over El-Hage et al. US 5,843,378 in view of Palasis 6,638,259.

El-Hage et al. teaches aspirating and dispensing probes are often used to transfer liquids between various vessels (plurality of vessel) and compartments in a chemical analyzer. The liquids typically include samples to be tested and reagents for testing the samples.

The probe successively aspirates reagents from reagent vessels and transfers the reagents to the reaction cuvette. After the sample-reagent mixture incubates in the

reaction cuvette, the probe transfers the reaction products to an analysis chamber (liquid analysis apparatus).

A preferred embodiment of the invention is illustrated in FIGS. 1-9. FIG. 1 shows a probe 10 for dispensing and aspirating liquid into and out of a vessel 14. Vessel 14 is held in a rack 16 which is mounted on a carousel. Probe 10 is attached to a probe positioning device, such as a mechanical arm 12. Arm 12 is designed to position probe 10 in an appropriate vessel for aspirating or dispensing liquid. Such mechanical arms for positioning probes are well known in the art.

FIG. 2 shows a cross sectional view of probe 10 (needle) and a portion of arm 12. Probe 10 includes an electrically insulative tube 18, an electrically conductive fluid conduit 26, and an electrically conductive rod 30. Conduit 26 and rod 30 are made of a relatively inert material so that they do not chemically react with sample and reagent liquids. The inert material is preferably stainless steel or gold-coated copper.

A washing station (rinsing means) is typically provided to wash the probe between aspirations of different substances.

El-Hage et al. do not disclose the needle as comprising a resin coating of polyetheretherketone (PEEK).

Palasis discloses a modified medical device for delivery of a pharmaceutically active material. For example, in the event that the medical device comprises a needle (or cannula) for delivery of the pharmaceutically active material, a polymeric needle can be fashioned from several of the materials listed above, notably polyimide, PTFE, PET,

polyphenylene sulfide (PPS), polysulfone (PS) and PEEK, which have excellent rigidity and the ability to be sharpened into a needle.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the needle of Palasis by coating it with PEEK material in order to ensure the integrity of the needle is maintained throughout a sterilization/washing process and to avoid corrosion.

5. Claims 3 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over King et al. US 6,132,582. in view of Palasis 6,638,259.

King et al. disclose a sample handling system in a multi-channel capillary electrophoresis apparatus is disclosed. The sample handling system includes a work surface for supporting a plurality of samples located at a plurality of work surface coordinates (plurality of vessels) and a sample loading assembly comprising a plurality of loading wells. At least one of the loading wells includes a capillary fixedly positioned therein. The system further includes a programmable sample transfer device for **automatically transferring** a sample from a work surface coordinate to a loading well.

The material used to fabricate the pipette (needle) will depend upon the requirements of a particular application. Factors to be considered include wetability, rigidity and conductivity. Where the sample is a liquid, the wetability of the pipette should be such that sample may be introduced into the pipette in a controlled and reproducible manner. When the pipettes are passively loaded with sample using capillary action, generally the pipette should be wetable by the sample material. It is preferable that the pipette be rigid in order to facilitate location of the inlet end of the

pipette with respect to the robot arm. Finally, where an electrical measurement is used in the tip sensor, the pipette should be electrically conductive. Preferred pipette materials include but are not limited to stainless steel, platinum and gold coated materials, glass, fused silica, and plastic or plastic coated materials, e.g., stainless steel coated with a parylene (synthetic resin).

The loading wells 20 located in the loading bar 150 include fluid passages 165 for introducing fluids into the loading wells, e.g., wash solvents for washing the loading wells between samples or electrophoresis buffer, and for removing fluids from the loading well, e.g., drying the loading wells after washing with wash solvents or removing residual sample after an injection step (column 7, line 65 – column 8, line 7).

Optionally, the sample loading assembly further provides a means for washing the exterior surface of a pipette associated with the sample transfer device 25. The capillary tubes 21 (liquid analysis apparatus) within which electrophoresis is performed are fixedly located in the loading wells during operation of the system (column 7, lines 49-55).

King et al. do not disclose the needle (pipette) as comprising a resin coating of polyetheretherketone (PEEK).

Palasis discloses a modified medical device for delivery of a pharmaceutically active material. For example, in the event that the medical device comprises a needle (or cannula) for delivery of the pharmaceutically active material, a polymeric needle can be fashioned from several of the materials listed above, notably polyimide, PTFE, PET,

polyphenylene sulfide (PPS), polysulfone (PS) and PEEK, which have excellent rigidity and the ability to be sharpened into a needle.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the needle of Polasis by substituting the coating with PEEK material in order to ensure the integrity of the needle is maintained throughout a sterilization/washing process and to avoid corrosion.

Allowable Subject Matter

6. Claim 1 and 18 are allowed.

7. The following is a statement of reasons for the indication of allowable subject matter: The prior art does not teach nor fairly suggest a needle of a non-noble base metal having an outer surface coated with a first coating material that includes a noble metal including platinum, a platinum group metal, or gold and an interior surface coated with a second coating of a thin film of quartz.

Conclusion

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Tomita, Masami et al.; Lee, Jeong S. et al.; Gambale, Richard A; Staples; Kary J. et al.; Speck; Ulrich et al.; Yoshikawa; Makoto et al.; Karkantis; Peter N. et al. disclose transfer devices.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian R. Gordon whose telephone number is 571-272-1258. The examiner can normally be reached on M-F, with 2nd and 4th F off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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